REPUBLIC OF KENYA

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

SUSPECTED ADVERSE DRUG REACTIONS AND THERAPEUTIC INNEFECTIVENESS FOLLOWING THE USE OF BUPIVACAINE HYDROCHLORIDE INJECTION (02/2024).

The Pharmacy and Poisons Board (the Board) is mandated under the Pharmacy and Poisons Act (Cap 244) to disseminate information on Health Products and Technologies (HPTs) to health professionals and the public to promote their rational use. The Board wishes to draw the attention of healthcare providers to the use of Bupivacaine HCL injection in anesthesia.

Bupivacaine is indicated for surgical anesthesia in a wide variety of superficial and invasive procedures. While Bupivacaine's benefits outweigh its risks, individual case safety reports received at the Pharmacy and Poisons Board (January 2021 to March 2024) have indicated a risk of severe adverse drug reactions following the use of bupivacaine hydrochloride injection. The reported events included convulsions, hypotension, confusion, irritability, loss of consciousness, rash, itchiness, and therapeutic failure. The outcomes of the reported events ranged from recovering to fatal.

The Board would therefore like to make the following recommendations to **healthcare practitioners**, specifically anesthetists and anesthesiologists to help minimize the above risks;

i. Before using bupivacaine hydrochloride, all procedure rooms must be equipped with the relevant emergency medications in the crash cart.
ii. Intraspinal and intrathecal bupivacaine hydrochloride should only be administered by a competent professional.
iii. Healthcare facilities to prepare detailed protocols for administration, monitoring of adverse events, and their management and provide in-house training on the proper use of Bupivacaine
iv. All anesthetic procedures be conducted under the proper supervision of an anesthesiologist.

v. Healthcare practitioners administering bupivacaine hydrochloride should be aware of the risk of serious adverse drug reactions that may occur and should monitor the patients for adverse events.

The Board is committed to monitoring the quality, safety, and efficacy of Bupivacaine and other HPTs in the Kenyan market.

The Board would like to thank the health care providers for the continued efforts to ensure the safe use of medicines and encourage them to provide feedback by contacting the Board at +254 795 743 040 or by sending an email to pv@ppb.go.ke or report any suspected adverse events or quality defects of Health Products and Technologies at http://pv.pharmacyboardkenya.org.

CHIEF EXECUTIVE OFFICER

30th SEPTEMBER 2024